Center for Scientific Review
National Institutes of Health

Scientific Areas of Integrated Review Groups (IRGs)

For a listing of the Scientific Review Administrator and membership roster for each study section, click on the study section roster next to the study section name under an IRG listed below or go to the study section index(study sections listed alphabetically) and click on the specified roster next to the name of the study section.

Last updated on the 31st October, 2003

Referral & Review

Renal and Urological Sciences IRG [RUS]

The Renal and Urological Sciences [RUS] IRG will review grant applications to investigate systemic or local diseases affecting the kidney, urinary tract, and male genital system. This includes clinical, translational and fundamental studies of the disease state and its treatment as well as of normal growth, development, structure, and function.

Specifically, the RUS IRG will review applications directed at understanding: 1) genetic, cellular and molecular mechanisms underlying regulation of fluid and mineral balance in the intact kidney and in the diverse cells composing the kidney; 2) pathogenesis of hypertension as it affects the kidney; 3) effects of hormonal functions on the kidney as a whole, normal and abnormal hormonal regulation of kidney and male sexual functions; 4) causes and treatment of acute and chronic disorders that affect the kidney, urinary tract, and male genital system (including sexual dysfunction); and 5) pathogenesis of local or systemic disorders affecting the structure or function of the kidney, urinary tract (including the pelvic floor), or the male genital system. In addition, the RUS IRG will review applications aimed at: 1) development and evaluation of new techniques for investigating disorders of the kidney, urinary tract, and male genital system; 2) development and evaluation of therapies to treat localized or systemic disorders arising from damage to the kidney, urinary tract, or male genital system; 3) translation of basic research to clinical investigation; and 4) treatment of disorders of the kidney, urinary tract, and male genital system.

The following Study Sections are included within the RUS IRG:

- Cellular and Molecular Biology of the Kidney [CMBK]
- Pathobiology of Kidney Disease [PBKD]
- Urologic and Kidney Development and Genitourinary Diseases

[UKGD]

- Renal and Urological Sciences Small Business Activities [SBIR/STTR] Special Emphasis Panel [RUS Small Business SEP]

Not all of the teams that will develop recommendations for other IRGs will have completed their deliberations before the study sections that compose the RUS IRG are implemented. Therefore, the proposed "shared interest" guidelines for each of the study sections listed below are tentative, pending further input from the remaining study section design teams, the community, and the CSR Advisory Committee to the Director, CSR.

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Cellular and Molecular Biology of the Kidney [CMBK]

[CMBK Roster]

The Cellular and Molecular Biology of the Kidney [CMBK] Study Section reviews grant applications involving basic and applied aspects of normal and abnormal renal physiology, cell biology, transport biology, including osmoregulation and osmosensing, hormone action and signal transduction, vascular biology, genetic disorders, cell-matrix interactions, biophysics, and bioenergetics.

Specific areas covered by CMBK:

- Molecular biology and physiology of transport systems (e.g., water channels, cotransporters, organic solutes, and ion channels) broadly relevant to renal function and disease; structure-function relationships; regulation of function; synthesis and degradation of cellular components; and disorders of transport function, both acquired and inherited.

- Protein trafficking and cell polarity; protein turnover and targeting; cell-matrix interactions; protein synthesis; and regulation of gene expression and other processes relevant to the function of renal tubular epithelial, vascular, and interstitial cells.

- Disorders of tubular epithelial and endothelial cells as they relate to kidney diseases.

- Identification and characterization of genes that cause kidney diseases in humans and animal models. Pathophysiology and cellular and molecular consequences of genetic disorders (including polycystic kidney disease and disorders of tubular function).

- Integrated aspects of disordered fluid, electrolyte, and acid-base homeostasis resulting from abnormalities in the transport systems; blood pressure and extracellular fluid volume homeostasis; hormonal and autocoid regulation of renal and urinary tract function; neural regulation; and abnormal transport systems causing hypertension.

- Pharmacology relating to kidney function.

CMBK has the following shared interests within the RUS IRG:

- **With Pathobiology of Kidney Disease [PBKD]**: (1) Hypertension: Applications related to the effects of hypertension or the hemodynamics of hypertension could be assigned to PBKD. Applications that focus on 1) the genetics of renal hypertension or vascular regulation or 2) cell physiology, transport, or channel abnormalities contributing to the development of hypertension, could be assigned to CMBK. (2) Genetic diseases. Applications related to organ physiology and consequences of genetic diseases could be assigned to PBKD. Also, studies that relate to alterations in the structure or function of the glomerulus could be assigned to PBKD. Applications related to genetic diseases affecting renal tubular epithelial cells, as well as those studying effects on the structure or function of affected proteins, could be assigned to CMBK. (3) Proteinuria and nephrotic syndrome. Studies of the pathogenesis of proteinuria and clinical studies of nephrotic syndrome could be assigned to PBKD, whereas studies of integrated handling of renal salt and water excretion in the pathogenesis of edema could be assigned to CMBK. (4) Progression of renal disease. Applications dealing with factors that influence the progression of disease or organ pathophysiology, whether clinical or in experimental models, are most appropriate for PBKD. Those that address cell physiology, including cell signaling, trafficking, polarity, transport or channel properties could be assigned to CMBK. (5) Diabetic nephropathy. Applications dealing with factors that influence the susceptibility to diabetic nephropathy, its initiation, progression, and pathophysiology (whether clinical or involving *in vivo* or *in vitro* experimental models) are most appropriate for PBKD. Those that address cell physiology (including cell signaling, trafficking, polarity, transport or channel properties) could be assigned to CMBK. (6) Pathogenesis and manifestations of cystic kidney disease. Clinical and basic studies of the effects of cystic diseases on renal function could be assigned to PBKD. Molecular and clinical genetic studies in humans and animal models are more appropriate for CMBK, as are studies of the transport properties of cystic epithelia.

- **With Urologic and Kidney Development and Genitourinary Diseases [UKGD]:** Applications related to pathogenesis of stone formation, the effects of stones, and treatment of stone disease could be assigned to UKGD. Applications related to abnormal transport systems and membrane biology related to stone formation could be assigned to CMBK.

CMBK has the following shared interests outside the RUS IRG:

- **With the Biological Chemistry and Macromolecular Biophysics [BCMB] IRG:** The BCMB IRG will not be implemented until later in 2004. In the interim, applicants may wish to review the guidelines for the BCS and BPC IRGs. Studies examining the structure and function of membranes or proteins involved in ion transport mechanisms, including signal transduction and bioenergetics, that address questions relative to the physiology or pathology of the kidney, are appropriate for CMBK. Studies designed to address general principles of ion transport, signal transduction or bioenergetics, and that use kidney elements primarily as a convenient source of material, may be considered under the auspices of the

BCMB IRG. In general, studies of kidney structure and function that use primarily biophysical techniques (e.g., X-ray crystallography, electron microscopy/image reconstruction, electron spin resonance, and single molecular techniques) would be assigned to the BCMB IRG.

- **With the Cell Biology [CB] IRG:** The CB IRG will not be implemented until later in 2004. In the interim, applicants may wish to review the guidelines for the CDF IRG. Applications related to general questions of epithelial cell biology with no apparent application to the kidney and its function could be assigned to the CB IRG. Applications related to questions of cell biology related to renal function and disease could be assigned to CMBK.

- **With the Genes, Genomes & Genetics [GGG] IRG:** The GGG IRG will not be implemented until later in 2004. In the interim, applicants may wish to review the guidelines for the GNS IRG. Studies directed at the renal or urological system could be assigned to CMBK if the focus is primarily on the elucidation of specific known disease mechanisms, molecules, or pathways in the genitourinary system. This would include the study of known genes or the use of established technologies to study non-Mendelian, complex diseases or Mendelian diseases. Applications that focus on general questions of gene discovery, genetic dissection of complex diseases, or development of emerging genetic technology could be assigned to GGG.

- **With the Biology of Development and Aging [BDA] IRG:** Studies of the kidney and aging are shared with the BDA IRG. Basic and clinical studies on aging that address questions specifically applicable to the kidney may be assigned to CMBK. Studies that use the kidney as a model to address questions having broad applicability for the biology of aging, or studies involving the kidney and interactions with age-related changes in other physiological systems could be assigned to the BDA IRG.

- **With the Cardiovascular Sciences [CVS] IRG:** Applications related to the molecular basis of disorders causing abnormal function of ion channels that result in hypertension may be assigned to either the CVS IRG or CMBK according to the central focus of the application. Applications related to non-renal aspects of hypertension may be assigned to the CVS IRG. Applications that focus on the genetics, vascular regulation, cell physiology, transport, or channel abnormalities contributing to the development of hypertension associated with renal insufficiency or end-stage renal disease may be assigned to CMBK.

- **With the Digestive Sciences [DIG] IRG:** Shared interests exist in areas such as renal transport mechanisms and drug therapy. Studies could be assigned to the DIG IRG when the kinetics, dynamics and mechanisms address disposition and effects of drugs where multiple organ systems are involved, or where the hepatic and/or gastrointestinal activities dominate. Pharmacology relating to kidney function and toxic injury to the kidney, including xenobiotic-mediated alterations, could be assigned to CMBK. This would include applications where multiple organ systems are involved if the transport systems are known to be essential for kidney function such as aquaporin or polycystin.

- **With the Integrative, Functional and Cognitive Neuroscience [IFCN]**

IRG: There is a shared interest in the neural control of renal function. Applications focusing on the central nervous system dealing with thirst could be assigned to the IFCN IRG. Applications on the central nervous system regulation of renal function could be assigned to CMBK.

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Pathobiology of Kidney Disease [PBKD]

[PBKD Roster]

The Pathobiology of Kidney Disease [PBKD] study section reviews grant applications involving basic and clinical studies of kidney disease. This includes investigations of pathophysiology, diagnosis, consequences and treatment of acute and chronic disorders of the kidney, the consequences of kidney disease and failure, as well as studies of the normal structure and function of the glomerulus. Studies may involve *in vivo* or *in vitro* models and/or patient-focused investigations.

Specific areas covered by PBKD:

- Normal structure and function of the glomerulus and its constituent cells, including normal cell biology of glomerular cells, composition and assembly of the glomerular basement membrane, cell-matrix interactions, and regulation of glomerular filtration and permeability.

- Immune and non-immune disorders of the glomerulus and tubulo-interstitium, including kidney-specific autoimmunity and renal manifestations of systemic autoimmune diseases, glomerulonephritis, non-inflammatory glomerulopathies, identification of nephritogenic antigens and antibodies, nephropathic cell-mediated immunity, and the role of inflammatory mediators and inflammatory cell infiltrates in the kidney.

- Proteinuria and nephrotic syndrome, including mechanisms and mediators of proteinuria as well as the pathophysiology of nephrotic syndrome and its consequences.

- Mechanisms of renal fibrosis and scarring, including post inflammatory fibrogenesis and the roles of proteinuria, ischemia, inflammatory mediators and immune mechanisms.

- Progression of renal disease, including risk factors and mechanisms of disease.

- Mechanisms and consequences of acute renal failure, including endothelial and epithelial cell injury, repair, and regeneration; contribution of inflammation; and mechanisms of cell death following ischemic injury and other forms of tubular epithelial injury.

- Toxic injury to the kidney, including xenobiotic-mediated alterations in renal signal transduction, cell-cycle regulation, receptors, genes, and apoptosis; as well as mechanisms of renal apoptosis and necrosis, senescence, genotoxic responses, DNA damage, oxidative stress, and

cellular aging.

- Renal hemodynamics, including the regulation of the renal microcirculation and the hormonal regulation of renal circulatory function.

- Role of the kidney in the regulation of blood pressure and in the development of hypertension, including hormonal and autocoid factors that regulate integrated functions of the kidney, including: renal hemodynamics; neural influences on the kidney; the renin-angiotensin system; and the expression of effects of nitric oxide, endothelin, and other such factors on the kidney.

- Effects of hypertension on the kidney, including experimental and clinical studies of the pathophysiology, course, and treatment of hypertensive nephrosclerosis.

- Vascular biology of the kidney. This includes renal vascular endothelial cell injury, dysfunction and involvement in inflammation, renovascular hypertension, and leukocyte homing to the renal microvasculature.

- Studies on basic and clinical aspects of kidney ablation, including experimental models and mechanisms of allograft rejection/tolerance, mechanisms of action of immunosuppression, biomarkers, immunogenetics, chronic allograft nephropathy, prevention and/or treatment of complications, and immunoregulatory protocols for prevention and/or treatment of rejection.

- Identification of biomarkers in renal disease, including both genomic and proteomic approaches.

- Diabetic nephropathy.

- Pathogenesis and manifestations of cystic kidney disease.

- Complications and management of uremia, including renal replacement therapies (including dialysis), the pathogenesis and consequences of abnormalities of the vascular or peritoneal access for dialysis therapy, metabolic and nutritional consequences of kidney disease (including those leading to uremic manifestations), and acquired cystic diseases.

- *In vitro* and animal models that investigate the molecular basis of "gene-environment" interactions related to the renal system focused on putative environmental susceptibility genes, and toxicogenetics.

PBKD has the following shared interests within the RUS IRG:

- **With Cellular and Molecular Biology of the Kidney [CMBK]:** (1) Proteinuria and nephrotic syndrome. Studies of renal salt and water handling in the pathogenesis of edema could be assigned to CMBK, whereas studies of the pathogenesis of proteinuria and clinical studies of the metabolic and nutritional consequences of the nephrotic syndrome could be assigned to PBKD. (2) Progression of renal disease. Applications

that address cell physiology, including cell signaling, trafficking, polarity, transport or channel properties could be assigned to CMBK. Those dealing with factors that influence the progression and whole organ pathophysiology, whether clinical or in experimental models are most appropriate for PBKD. (3) Renal hemodynamics. Hypertension resulting from, or causing, changes in cell physiology, transport, or channel abnormalities contributing to the development of hypertension could be assigned to CMBK. Applications that focus on the genetics of renal hypertension or its influence on vascular cells (endothelial and smooth muscle cells) in the kidney leading to abnormal vascular regulation could be assigned to CMBK. Applications related to the effects of hypertension on the kidney or changes in hemodynamics related to hypertension could be assigned to PBKD. (4) Identification of biomarkers in renal disease. Applications related to the molecular nature of proteins causing renal disease and its relationship with epithelial cells could be assigned to CMBK. Studies of biomarkers derived from the kidney to inform understanding of the diagnosis/treatment of kidney diseases as well as those related to genetic disorders of the glomerulus and blood vessels could be assigned to PBKD. (5) Diabetic nephropathy. Applications dealing with cell physiology, including cell signaling, trafficking, polarity, transport or channel properties could be assigned to CMBK. Those that address factors that influence the susceptibility to diabetic nephropathy, its initiation, progression, and pathophysiology (whether clinical or in *in vivo* or *in vitro* experimental models) are most appropriate for PBKD. (6) Pathogenesis and manifestations of cystic kidney disease. Molecular and clinical genetic studies in humans and animal models are more appropriate for CMBK as are studies of the transport properties of cystic epithelia. Clinical and basic studies of the effects of cystic diseases on renal function could be assigned to PBKD.

- **With Urologic and Kidney Development and Genitourinary Diseases [UKGD]:** (1) Problems of divalent ion metabolism and stone formation following renal transplantation could be reviewed by PBKD if the application emphasizes renal physiology or pathology. Applications designed to resolve post-transplant obstructive complications, bladder reconstruction, kidney stone formation or other urological issues could be reviewed by UKGD. (2) In general, these studies will be assigned to UKGD, except when the lower urinary tract is involved in a disorder affecting the kidney, and for which PBKD has specific expertise (e.g., vasculitic syndromes, systemic lupus erythematosus).

PBKD has the following shared interests outside the RUS IRG:

- **With the Biological Chemistry and Macromolecular Biophysics [BCMB] IRG:** The BCMB IRG will not be implemented until later in 2004. In the interim, applicants may wish to review the guidelines for the BCS and BPC IRGs. Studies of metalloproteinases in kidney physiology or pathophysiology could be assigned to PBKD. If the structure/function of metalloproteinases is the main focus, the application could be assigned to the BCMB IRG. Studies that focus on renal bioenergetics in renal damage, acute renal failure or diabetic nephropathy could be reviewed in PBKD. Studies designed to address only general principles of bioenergetics and that use kidney elements primarily as a convenient source of material, may be considered under the auspices of the BCMB

IRG.

- **With the Cell Biology [CB] IRG:** The CB IRG will not be implemented until later in 2004. In the interim, applicants may wish to review the guidelines for the CDF IRG. (1) When the focus of the application is on glomerular cell and structural biology and the interaction with the extracellular matrix, assignment could be to PBKD. If the application uses glomerular cells to study a universal process in cell biology, assignment could be to the CB IRG. (2) Applications that focus on the general process of fibrosis and scarring could be assigned to the CB IRG. Fibrosis of the renal interstitium resulting from glomerular and/or tubular diseases could be assigned to PBKD. (3) Applications that focus on the development of proteinuria, which may involve alterations in the biology of glomerular cells and/or cell-matrix interactions, could be assigned to PBKD. Studies of basic cell injury or death (with protein leakage), could be assigned to the CB IRG. (4) Applications dealing with toxin-mediated, acute or chronic cell injury within the kidney, including proton secretion and water transport, could be assigned to PBKD. Use of toxins to probe general cellular activities, such as membrane transport or trafficking or to determine the function of cellular organelles could be assigned to CB.

- **With the Biology of Development and Aging [BDA] IRG:** Studies of the kidney and aging are shared with the BDA IRG. Basic and clinical studies on aging that address questions specifically applicable to the kidney may be assigned to PBKD. Studies that use the kidney as a model to address questions having broad applicability for the biology of aging, or studies involving the kidney and interactions with age-related changes in other physiological systems could be assigned to the BDA IRG.

- **With the Bioengineering Sciences and Technologies [BST] IRG:** Applications focused on the use of genomic and proteomic data to identify biomarkers in renal disease could be assigned to PBKD. If the primary focus is combining experimental validation and modeling technology or related analyses of biological data, i.e., bioinformatics, or basic methodology for data management and analysis, assignment could be to the BST IRG.

- **With the Health of the Population [HOP] IRG:** Studies directed at proteinuria and nephrotic syndrome as risk factors could be assigned to the HOP IRG. Studies of the pathogenesis of proteinuria and clinical studies of the metabolic and nutritional consequences of the nephrotic syndrome could be assigned to PBKD.

- **With the Immunology [IMM] IRG:** (1) Studies of autoimmunity and humoral and cellular immune responses that focus on renal or urinary tract function could be assigned to PBKD. These include clinical and animal studies of glomerulonephritis, interstitial nephritis, lupus nephritis and vasculitic syndromes as they affect the kidneys and urinary tract. Immunological events leading to autoimmunity could be assigned to the IMM IRG. (2) Applications dealing with transplantation immunology (e.g., rejection/tolerance) could be assigned to the IMM IRG. Applications that focus on the functional consequences of kidney transplantation could be assigned to PBKD.

- **With the Hematology [HEME] IRG:** Studies of blood cells could be

assigned to the HEME IRG. Studies of renal injury caused by blood cells or blood cell migration into the kidney could be assigned to PBKD.

- **With the Cardiovascular Sciences [CVS] IRG:** (1) Applications addressing general vascular problems, including proliferation, could be assigned to the CVS IRG. Applications to investigate the vascular biology of renal vessels could be assigned to PBKD. Applications that consider problems related to vascular access for hemodialysis could be assigned to PBKD. (2) Studies directed at the mechanisms of atherogenesis could be assigned to the CVS IRG. Applications that focus on renal injury as a result of atherogenesis, including proteinuria and nephrotic syndrome, could be assigned to PBKD. (3) PBKD may be assigned applications that involve basic and clinical studies of the complications of decreased renal function and manifestations of uremia. Applications where uremia reflects an abnormality of the cardiovascular system may be best assigned to the CVS IRG. (4) Assignment of applications related to hypertension, including the role of renal hemodynamics, tubular function, and renal humoral/hormonal agents, may be made to either the CVS IRG or PBKD based on the central focus of the study. Other aspects of renal hemodynamics, tubular function, and renal humoral/hormonal agents as they affect renal function may be assigned to PBKD. Clinical studies of hypertension would generally be assigned to the CVS IRG, but hypertension associated with renal insufficiency or end-stage renal disease would be assigned to PBKD.

- **With the Endocrinology, Metabolism, Nutrition and Reproductive Sciences (EMNR) IRG:** The EMNR IRG will not be implemented until 2004. In the interim, applicants may wish to review the guidelines for the ENR and the NMS IRGs. (1) Proteinuria and nephritic syndrome. Studies directed at the mechanisms of hyperlipidemia could be assigned to the EMNR IRG. If hyperlipidemia is studied as a possible cause of renal disease, the application could be assigned to PBKD. (2) Diabetic nephropathy. Applications dealing with factors that influence the susceptibility to diabetic nephropathy, its initiation, progression and pathophysiology may be appropriately assigned to PBKD. Applications that focus on extra-renal manifestations of diabetes could be assigned to the EMNR IRG. Basic and clinical studies of the metabolic or nutritional complications arising from kidney disease and leading to manifestations of uremia could be reviewed in PBKD if the focus is on renal function. Applications that focus on generalized effects of nutrient metabolism in diabetic nephropathy and diabetes induced metabolic abnormalities may be assigned to the EMNR IRG.

- **With the Digestive Sciences [DIG] IRG:** Because the kidney and the liver are major organs involved in the metabolism of drugs, shared interests exist in transport mechanisms, drug therapy and toxicity. If the metabolism or toxicity is mediated by the kidney or affects the kidney, the application could be assigned to PBKD. Studies could be assigned to DIG when the kinetics, dynamics and mechanisms address disposition and effects of drugs where multiple organ systems are involved, or where the hepatic and/or gastrointestinal activities dominate.

- **With the Surgical Sciences, Biomedical Imaging, and Bioengineering [SBIB] IRG:** The SBIB IRG will not be implemented until 2004. In the interim, applicants may wish to review the guidelines for the SRB IRG. (1)

The SBIB IRG would be an appropriate assignment for surgical aspects of transplantation and issues involving recovery of organs for transplantation and organ preservation. Transplantation applications with direct implications for kidney function could be reviewed in the PBKD Study Section. (2) Studies of biomarkers derived from the kidney to inform understanding and diagnosis/treatment of kidney diseases could be assigned to PBKD. Studies of markers of function, such as might be developed for the radiological diagnosis of distribution of renal blood flow or epithelial cell function, could be assigned to the SBIB IRG. (3) Cell-cell interactions that determine functional alterations resulting from both acute and chronic events in the kidney could be assigned to PBKD. Studies primarily dealing with surgical outcomes or with applied radiologic imaging could be assigned to the SBIB IRG.

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Urologic and Kidney Development and Genitourinary Diseases [UKGD]

[UKGD Roster]

The Urologic and Kidney Development and Genitourinary Diseases [UKGD] study section reviews grant applications concerning normal and abnormal development of the kidney, urinary tract, and male genital system and physiologic and pathophysiologic processes of cells and tissues of the bladder, prostate, ureter, urethra, male reproductive organs, penis and male and female pelvic floor. This encompasses: 1) responses of uroepithelial tissues and cells to infectious bacteria and other pathologic insults; 2) mechanisms of renal stone formation and prevention; 3) normal development of the kidney, urinary tract, and male genital system; 4) normal and pathophysiological processes of the urinary tract and male genital system; 5) application of new technologies and methodologies to the diagnosis and treatment of urologic diseases; 6) novel approaches to regeneration and tissue engineering of the kidney, urinary tract and male genital system; and 7) clinical assessment of genitourinary diseases including urinary incontinence and pelvic floor dysfunction.

Specific areas covered by UKGD:

- Development, cell growth, differentiation, aging, and pre-neoplastic conditions in the kidney and the urinary tract and male genital system. This includes: genetic and environmental mechanisms controlling growth, differentiation, and development (including the embryonic origin, commitment, differentiation, and fate) of all cell types in the kidney, urinary tract, and male genital system; cell and tissue interactions that regulate organ development; inductive mechanisms of tissue and organ development; lineage determination; pattern formation; morphogens, cytokines, hormones, and cell cycle mechanisms that control normal and abnormal growth and differentiation; nuclear and mitochondrial mechanisms responsible for aging; and signals underlying senescence.

- Responses to, and consequences of, microbial infection and inflammation in the urinary tract and male genital system. This includes proposals to elucidate the molecular basis of acute and recurrent urinary tract infections. Included are studies that focus on: 1) understanding the mechanism by which inflammatory processes of the urinary tract and male

genital system relate to disease; and 2) understanding the molecular and cellular consequences of host-pathogen interactions (including *E. coli* and other microbial pathogens) and inflammatory processes in the urinary tract including angiogenesis, signaling pathways, apoptosis, and innate immune responses. Diseases include urinary tract infection, interstitial cystitis, prostatitis, pyelonephritis, and local inflammatory responses.

- Divalent ion metabolism/stones. This area relates to mechanisms of stone formation (including metabolic dysregulation, etiologic agents and divalent cations); natural inhibitors of stone formation; stone detection, treatment and prevention; and effects of stone treatment on cells of the kidney, urinary tract, and male genital system.

- Function and dysfunction of the bladder, ureter, and urethra. This includes: basic and preclinical studies of hypertrophic muscle growth; contractile dysfunction; effects of aging; prostatic hyperplasia and obstruction; pediatric conditions (such as posterior urethral valve disorders, obstructive uropathy, vesico-ureteral reflux and bladder exstrophy); pelvic pain syndromes; neurogenic syndromes; spinal cord influences on bladder function and feedback regulation; cell and tissue interactions; and signal transduction mechanisms as they relate to urologic diseases or conditions.

- Function and dysfunction of the prostate. This includes: basic and preclinical studies of the relationship between pre-neoplastic conditions and frank neoplasia; development and progression of benign prostatic hyperplasia; stroma-epithelial interactions and cell signaling; signal transduction mechanisms as they relate to prostate cell growth and survival (including steroid-mediated signaling mechanisms); and cell-matrix interactions.

- Male and female incontinence and pelvic floor dysfunction. This area relates to the problems of urinary incontinence and pelvic organ prolapse and organ, tissue, cellular, and molecular mechanisms affecting incontinence and pelvic organ function. It includes studies of: normal structure, function and biomechanics as applied to the urethra, bladder and their supporting tissues. Studies of smooth and striated muscles, connective tissue, and nerves supplying the pelvic floor are considered relevant, as are studies of normal development, injuries sustained during childbirth, and deterioration that occurs with age and disease.

- Male reproductive tract. This area includes basic and clinical studies related to normal and abnormal function of the testis, epididymis, *vas deferens*, and seminal vesicles. Studies of the effects of disease, environment, and pharmacologic agents on these organs are included.

- Sexual dysfunction. This area includes basic and preclinical studies of both female and male normal sexual function and dysfunction (e.g., erectile dysfunction or anorgasmia) as well as the effects of: disease (such as diabetes and cardiovascular disease), toxic environments (e.g., cigarette smoking), and licit and illicit drugs on sexual function.

- Cell and gene therapy of the kidney or genitourinary tract. This area includes technologies, animal models, and human studies that utilize cell and gene therapy to alter or repair abnormal functions of the kidney, urinary tract, and male genital system.

- Regeneration and tissue engineering of the kidney, urinary tract, and male genital system. This area includes: 1) stem cell biology and cellular therapeutics as they relate to the kidney, urinary tract, and male genital system (including differentiation of embryonic and adult stem cells into the various kidney, urinary tract, and male genital system cell types); 2) artificial scaffolding, biopolymers, and vector systems to generate specific tissues and/or organs, epithelial and vascular repair and remodeling in response to injury; and 3) novel cell and gene therapies.

- Clinical research and outcomes. This includes: investigator-initiated clinical trials and other human research studies that involve urologic diseases and disorders.Molecular and cell biology of bone, cartilage, tendon, and ligament injury and repair.

- Application of novel technologies to studies of the genitourinary tract. This includes the application of new technologies (including proteomics, microarrays and nanotechnology) to characterize disease states; develop and validate new clinical, diagnostic, or prognostic tests; and evaluate treatment outcomes.

UKGD has the following shared interests within the RUS IRG:

- **With Cellular and Molecular Biology of the Kidney [CMBK]:** Applications related to abnormal transport systems and membrane biology related to mineral balance could be assigned to CMBK. Applications related to pathogenesis of stone formation, the effects of stones, and their treatment could be assigned to UKGD.

- **With Pathobiology of Kidney Disease [PBKD]:** (1) Problems of divalent ion metabolism and stone formation following renal transplantation could be reviewed by PBKD if the application emphasizes renal physiology or pathology. Applications designed to resolve post-transplant obstructive complications, bladder reconstruction, kidney stone formation or other urological issues could be reviewed by UKGD. (2) In general, these studies will be assigned to UKGD except when the lower urinary tract is involved in a disorder affecting the kidney, and for which PBKD has specific expertise (e.g., vasculitic syndromes, systemic lupus erythematosus).

UKGD has the following shared interests outside the RUS IRG:

- **With the Biological Chemistry and Macromolecular Biophysics [BCMB] IRG:** The BCMB IRG will not be implemented until later in 2004. In the interim, applicants may wish to review the guidelines for the BCS and BPC IRGs. Studies examining divalent metal metabolism that address questions directly relevant to the physiology or pathology of the genitourinary tract are appropriate for UKGD. Studies designed to address general metallobiochemistry or divalent metal metabolism not directly related to genitourinary tract function] may be considered under the auspices of the BCMB IRG. Studies of metalloproteinases in genitourinary organ physiology or pathophysiology could be assigned to UKGD. If the structure/function of metalloproteinases is the main focus, the BCMB IRG could be assigned the application. In general, studies of

genitourinary tract structure and function that use primarily biophysical techniques (e.g., X-ray crystallography, electron microscopy/image reconstruction, electron spin resonance, and single molecular techniques) would be assigned to the BCMB IRG.

- **With the Genes, Genomes and Genetics [GGG] IRG:** The GGG IRG will not be implemented until later in 2004. In the interim, applicants may wish to review the guidelines for the GNS IRG. Studies directed at therapeutic approaches to genetic disease(s) of the kidney or genitourinary tract, including gene and protein replacement therapy, could be assigned to the UKGD. Assignment could be to the GGG IRG if the question(s) addressed are applicable to multiple diseases or organ systems, or if the study involves an emerging approach for which expertise resides only in the GGG IRG.

- **With the Biology of Development and Aging [BDA] IRG:** (1) The BDA IRG may be assigned applications on basic, early developmental mechanisms involved in formation of organ primordia. Development of organs such as the bladder, kidney or prostate may be assigned to UKGD. Studies involving differentiation of kidney physiology or the physiology and function of other developed organs (such as the bladder or prostate) may also be assigned to UKGD. Overlapping interests with BDA IRG may include stem cells, apoptosis, and regulation of cell cycle. (2) Studies primarily focused on a single organ or system, such as the renal or urological systems, or a specific disease in which age-related interactions or changes of function are a minor or secondary component could be assigned to UKGD. Studies in which the focus is aging, particularly those that transcend single organ systems or disciplines, could be assigned to BDA

- **With the Bioengineering Sciences and Technologies [BST] IRG:** (1) Applications focused on specific kidney or genitourinary stem cell or gene transfer therapies are relevant to UKGD. Applications focused on developing stem cell and gene transfer technologies to introduce genes and drugs in a general context are relevant to BST IRG. (2) Applications focused on the use of genomic or proteomic data in characterizing genitourinary tract diseases or developing diagnostic or prognostic tests for these diseases could be assigned to PBKD. If the primary focus is combining experimental validation and modeling technology or related analyses of biological data (i.e., bioinformatics), or basic methodology for data management and analysis, assignment could be to the BST IRG. (3) Applications that use nanotechnology for genitourinary tract diagnostic procedures may be assigned to UKGD. Where the dominant emphasis of the proposal is the technology or instrumentation the proposal may be assigned to BST. (4) Applications focused on the use of medical implant materials for genitourinary tract disorders and dysfunctions may be assigned to UKGD. Applications on general biocompatibility and new material development could be assigned to the BST IRG.

- **With the Health of the Population [HOP] IRG:** Applications on the complex epidemiology of renal or urology health or disease should be assigned to the HOP IRG.

- **With the Immunology [IMM] IRG:** Studies of inflammatory processes or innate immunity when the focus is on urinary tract function could be

assigned to UKGD. When the focus is on the immune system assignment could be to the IMM IRG.

- **With the Infectious Diseases and Microbiology [IDM] IRG:** Studies of microbial genetics, bacteriology and investigations focused on urologically pathogenic microbes could be assigned to the IDM IRG. Basic and clinical studies focused on understanding the functional consequences of such host-pathogen interactions and how they relate to outcome, clinical syndromes, or host responses could be assigned to UKGD.

- **With the Oncological Sciences [ONC] IRG:** Investigation of malignant transformation and progression focused on mechanisms applicable to neoplastic processes in general, could be assigned to the ONC IRG. Applications focused on malignant transformation or progression in the context of urinary tract or kidney development or disease, or comparisons of benign and malignant cells of kidney, urinary tract, or male genital system for the purpose of understanding normal or benign processes in these organs could be assigned to UKGD. In addition, certain genes and their products are involved in both neoplastic and developmental process (e.g. WT1 and VHL). Therefore, certain applications that focus on the role of such genes on kidney or urogenital gene regulation, or on normal or abnormal development of the kidney, urinary tract, or male genital system could be assigned to UKGD. When applications focus on the role of such genes in neoplasia they could be assigned to the ONC IRG.

- **With the Endocrinology, Metabolism, Nutrition and Reproductive Sciences [EMNR] IRG:** The EMNR IRG will not be implemented until 2004. In the interim, applicants may wish to review the guidelines for the ENR and the NMS IRGs. There is shared interest between three study sections, the Molecular and Cellular Endocrinology (MCE) and the Cellular, Molecular and Integrative Reproductive Sciences (CMIR) in the EMNR IRG, and UKGD. The areas of shared interest include male reproductive biology and the male reproductive tract, including the prostate. The perspective of the applicant should determine assignment, but in general, the central focus of applications reviewed in CMIR is on reproductive competency (e.g., the role of prostatic fluids in sperm motility), while the focus of UKGD is urology (e.g., Benign Prostatic Hyperplasia (BPH), including its effect on urinary tract function), and the focus in MCE is on fundamental mechanisms of hormone action (e.g., mechanisms of testosterone signal transduction as found in the prostate). An application on the non-cancer prostate can be reviewed in any one of at least three study sections depending on the primary focus. Similarly, while CMIR will review the full spectrum of reproductive sciences, including cellular, molecular and clinical studies, UKGD could review research in clinical urology, particularly in the areas of male infertility and sexual function.

- **With the Musculoskeletal, Oral and Skin Sciences [MOSS] IRG:** Basic research studies of the development or mechanism of action of bone, muscle and connective tissue could be assigned to the MOSS IRG. Studies of the role of bone, muscle and connective tissue in normal or pathological states of the urological system could be assigned to UKGD.

- **With the Surgical Sciences, Biomedical Imaging, and Bioengineering [SBIB] IRG:** The SBIB IRG will not be implemented until 2004. In the

interim, applicants may wish to review the guidelines for the SRB IRG. Applications can be referred to UKGD when the emphasis is on using imaging systems to obtain structural or functional information, or used in diagnosis or therapy, of the genitourinary track. When the emphasis of an application is on the design, development or validation of medical imaging systems, their components, or software, assignment could be to the SBIB IRG. Studies involving tissue engineering could be referred to UKGD or the SBIB IRG depending on the focus of the study, with UKGD focused on specific applications to the genitourinary track. When the emphasis is on the integration of physical, chemical, mathematical or engineering principles in the design and development of engineered constructs assignment could be to the SBIB IRG.

- **With the Integrative, Functional and Cognitive Neuroscience [IFCN] IRG:** There is a shared interest in neuronal mechanisms of pain in conditions such as interstitial cystitis and prostatitis. Applications focusing on the encoding or modulation of pain in the nervous system could be assigned to the IFCN IRG. Applications on the central nervous system regulation of urological function where pain is not the central focus could be assigned to UKGD.

- **With the Brain Disorders and Clinical Neuroscience [BDCN] IRG:** Applications may be assigned to BDCN if neurogenic bladder or other bladder problems are secondary to spinal cord injury. Other aspects of central nervous system regulation of urological function where pain is not the central focus could be assigned to UKGD.

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Renal and Urological Sciences Small Business Activities [SBIR/STTR] Special Emphasis Panel [RUS Small Business SEP]

[SBIR/STTR Study Section Rosters]

The Renal and Urological Sciences Small Business Activities Special Emphasis Panel [RUS Small Business SEP] will review SBIR and STTR grant applications that focus primarily on kidney, urinary tract, and male genital system therapies, devices, and diagnostics. This includes clinical, translational and fundamental studies and investigators may employ a range of approaches that include genetics, genomics and proteomics, molecular, cell, and computational biology, biochemistry, biophysics and bioengineering, imaging, analyses of model organisms, and human studies.

Specific areas covered by the RUS Small Business SEP:

- Development and evaluation of new techniques for investigating, diagnosing and treating disorders of the kidney, urinary tract, and male genital system;
- Development of new techniques and evaluation of the efficacy of dialysis;
- Application of new technologies and methodologies to the diagnosis and treatment of urologic diseases;
- Novel approaches to regeneration and tissue engineering of the kidney, urinary tract and male genital system; and,

- Clinical assessment of genitourinary diseases including urinary incontinence and pelvic floor dysfunction.

The RUS Small Business SEP has the following shared interests outside the RUS IRG:

- **With the Biological Chemistry and Macromolecular Biophysics [BCMB] IRG:** The BCMB IRG will not be implemented until later in 2004. In the interim, applicants may wish to review the guidelines for the BCS and BPC IRGs. Studies examining the structure and function of membranes or proteins involved in kidney physiology or pathophysiology could be assigned to the RUS Small Business SEP. Studies examining the general principles of membrane or protein structure and function that use renal tissue as a convenient source of material could be assigned to the BCMB IRG.

- **With the Biology of Development and Aging [BDA] IRG:** Applications studying the use of stem cell technology for renal or genitourinary tract specific issues could be assigned to the RUS Small Business SEP. BDA may be considered for more general developmental studies. Applications that use human embryonic stem cells might also be clustered in the BDA IRG, even if studying renal or urological system specific issues.

- **With the Risk, Prevention, and Health Behavior [RPHB] and the Health of the Population [HOP] IRGs:** Studies of behavior modification, including patient health education or training, directed toward the prevention and treatment of renal and urological system diseases, including psychological aspects, could be assigned to the RPHB IRG, or to the HOP IRG, depending on the level of analysis and the nature of the intervention. Applications on the diseases, disorders, or functional consequences of behaviors could be assigned to the RUS Small Business SEP. Health education or training directed to the health care provider, not the patient, should also be assigned to the RUS Small Business SEP.

- **With the Oncological Sciences [ONC] IRG:** Studies of diagnosis, prevention, treatment, and epidemiology of renal or urological cancers, including prostate cancer, would be assigned to the ONC IRG or to the HOP IRG, depending on the level of analysis. Applications focusing upon large numbers of persons or aggregates of persons would be assigned to the HOP IRG. Applications focusing on dysplasia and hyperplasia should be considered by the RUS Small Business SEP or to the HOP IRG, depending upon the level of analysis and the number of persons studied.

- **With the Surgical Sciences, Biomedical Imaging, and Bioengineering [SBIB] IRG:** The SBIB IRG will not be implemented until 2004. In the interim, applicants may wish to review the guidelines for the SRB IRG. (1) The SBIB IRG would be an appropriate assignment of applications focused on surgical aspects of transplantation and issues involving recovery of organs for transplantation and organ preservation. Applications that primarily address the implications of transplantation on kidney function could be reviewed in the RUS Small Business SEP. (2) Studies of biomarkers derived from the kidney to inform understanding and diagnosis/treatment of kidney diseases could be assigned to the RUS Small Business SEP. Studies of markers of function, such as might be

developed for the radiological diagnosis of distribution of renal blood flow or epithelial cell function, could be assigned to the SBIB IRG. (3) Cell-cell interactions that determine functional alterations resulting from both acute and chronic events in the kidney could be assigned to the RUS Small Business SEP. Studies primarily dealing with surgical outcomes or with applied radiologic imaging could be assigned to the SBIB IRG. (4) Applications can be referred to the RUS Small Business SEP when the emphasis is on using imaging systems to obtain structural or functional information, or used in diagnosis or therapy, of the genitourinary track. When the emphasis of an application is on the design, development or validation of medical imaging systems, their components, or software, assignment could be to the SBIB IRG. (5) Studies involving tissue engineering could be referred to the RUS Small Business SEP when focused on specific applications to the genitourinary track. When the emphasis is on the integration of physical, chemical, mathematical or engineering principles in the design and development of engineered constructs assignment could be to the SBIB IRG.

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